




Background


- 11/91 - Project launched
 - ◆ Task force/working group formed
- 2/92 - Working Group Report issued
 - ◆ Issues identified
 - ◆ Actions recommended
- 7/92 - Advance Notice published
 - ◆ 12/92 Extended comment period ends



more ...

Background

- 1993 - Proposed Rule Drafted
- 8/31/94 - Proposed Rule Published
 - ◆ 11/29/94 Comment period ends
- ???? - Final Rule Published
 - ◆ ???? - Final Rule Effective

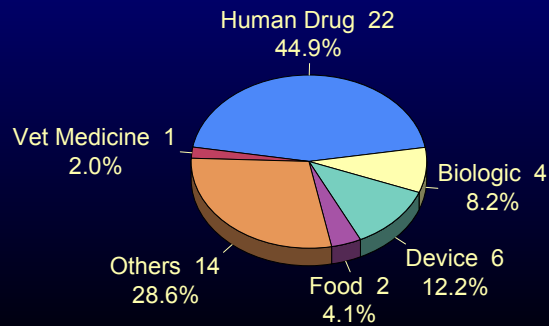


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Proposed Rule: Purpose

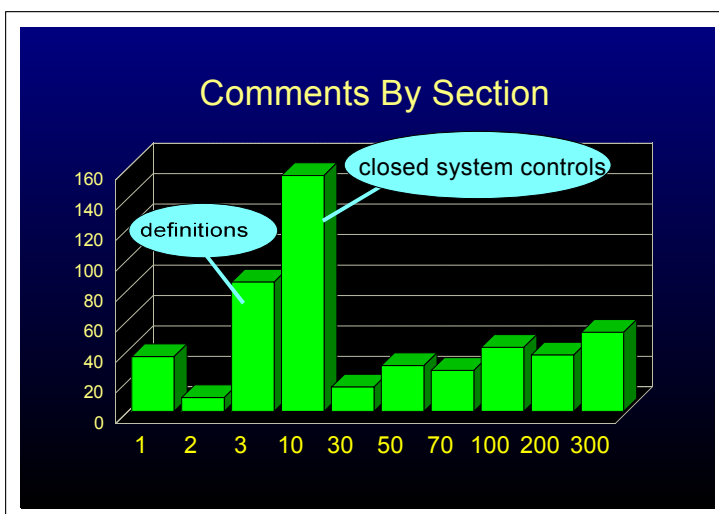
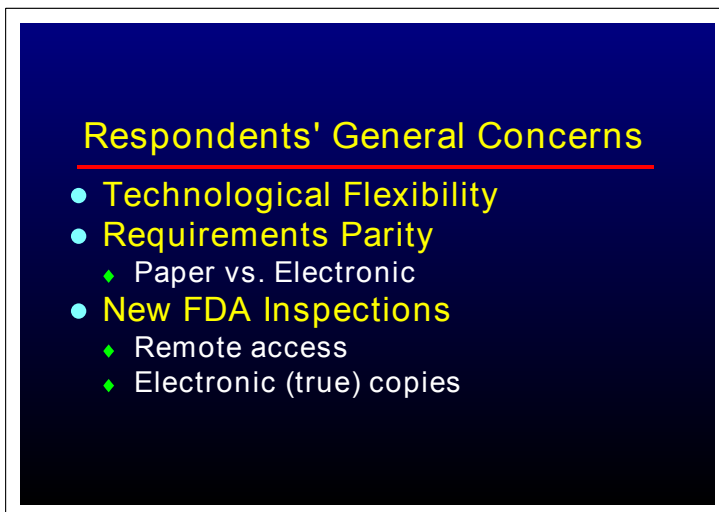
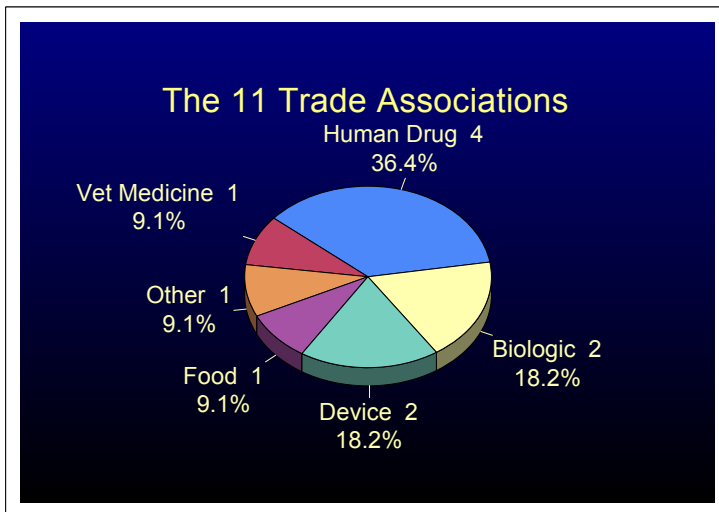
- Accept and Promote New Technologies
- Maintain FDA Enforcement Integrity
 - ◆ Review/Copy records
 - ◆ Document individual responsibility
 - ◆ Investigate falsification
 - ◆ Pursue legal actions

The 49 Respondents

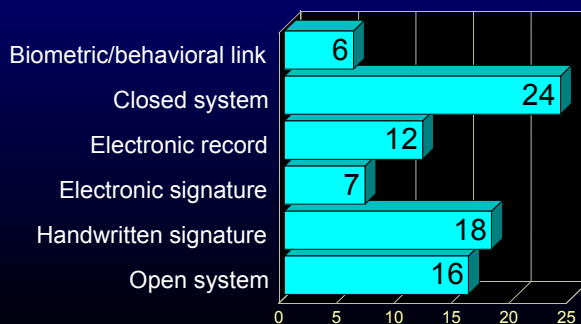


Other Respondents:

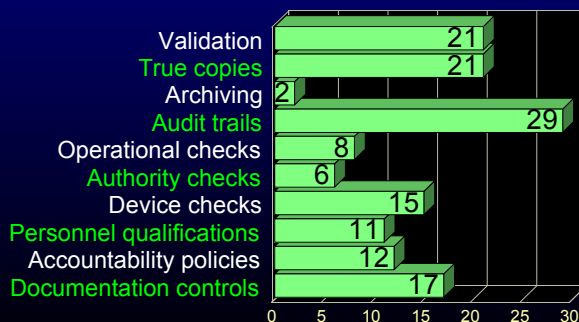
Consultants:	3
System developers:	3
Attorneys:	2
Non-specific firms:	2
Non-specific association:	1
Individual:	1
Federal agency:	1
Delivery service:	1



Comments on Terms



Comments on controls



Respondents' Specific Concerns

- Open/Closed system definitions
- True Copies to FDA
- Time stamped audit trails
- Signature manifestations
- Signature/record binding
- Certification to FDA
- Identification device testing

§ 11.3 Definitions

Closed System:

An environment where there's communication among multiple persons, where system **access is restricted** to people who are **part of the organization** that operates the system.



[more ...](#)

§ 11.3 Definitions

Open System:

An environment where there's communication among multiple persons, where system **access extends** to people who are **not part of the organization** that operates the system.



[more ...](#)

Closed and Open Systems §11.3(b)(4)&(8)

- **Problem:**
 - ◆ Definition too narrow
 - Excludes Contractors
- **Solution?:**
 - ◆ Change from unit membership to system access control

§11.10 Controls for Closed Systems

- Able to generate true copies
 - ◆ Human readable form
 - ◆ Electronic form
 - ◆ Suitable for FDA
 - Inspection
 - Review
 - Copying

more ...

True Copies in Electronic Form §11.10(b)

- Problem:
 - ◆ Retain supplanted systems
 - True = file formats
 - ◆ Give FDA electronic cc's
- Solution?:
 - ◆ Change "true" to "complete and accurate"
 - ◆ Retain electronic copy provision

§11.10 Controls for Closed Systems

- Time stamped audit trail shows:
 - ◆ Changes
 - Don't obscure prior info.
 - ◆ Write to file operations
 - ◆ Operator entries/actions

more ...

Time Stamped Audit Trails §11.10(e)

- **Problem:**
 - ◆ Covers too much
 - e.g., temp. system files
 - ◆ Recording time unnecessary
- **Solution?:**
 - ◆ Limit to info in comparable paper records
 - ◆ Retain time as vital to:
 - complete documentation
 - deter falsification

§ 11.50 Signature Manifestations

- **E-record must show:**
 - ◆ Signer's printed name
 - ◆ Date/time of signing
 - ◆ Meaning of signature:
 - e.g., review, approval

Signature Manifestations §11.50

- **Problem:**
 - ◆ Embedding info in record
 - need more flexible links to info
 - ◆ Recording time of signing unnecessary
- **Solution?:**
 - ◆ Change from embedding to info linkage
 - ◆ Retain time as vital to:
 - complete documentation
 - deter falsification

§ 11.70 Signature/record Binding

- Ensure against record falsification:
 - ♦ Sigs. can't be:
 - excised/copied/transferred
- Applies to e-sigs and handwritten sigs. on e-records.

Signature/Record Binding §11.70

- Problem:
 - ♦ Embedding info in record
 - need more flexible links to info
 - passwords in records
- Solution?:
 - ♦ Change from embedding to info linking

§ 11.100 General Requirements

- Certify to FDA, system's e-sigs:
 - ♦ Authentic
 - ♦ Valid
 - ♦ Binding
- Certify specific e-sig, per request
- Send certification to FDA district office

Certification to FDA §11.100(c)

- **Problem:**
 - ◆ "Guarantee" is unattainable absolute
 - ◆ Contrary to other sections
 - ◆ Unprecedented
 - ◆ Unwarranted
- **Solution?:**
 - ◆ Recast legal equivalency certification
 - E-sig = handwritten signature

§ 11.300 Controls for Identification Codes/Passwords

- **Test id devices (e.g., token, card):**
 - ◆ For proper functioning
 - ◆ Periodically

Identification Device Testing §11.300(e)

- **Problem:**
 - ◆ Unnecessary
 - Devices tested per ea. use
 - Devices fail "safe" (deny access)
- **Solution?:**
 - ◆ Clarify intent to test for:
 - unauthorized modification
 - wear and tear

Future Guidance

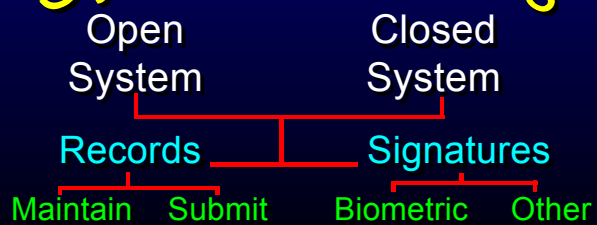
- Passwords
- Digital signatures
- Audit trails
- Software validation
- Identity verification

more ...

Future Guidance

- Electronic submissions
- Device checks
- Token (card) controls
- Signature to record linking

System Controls





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